biomedical diagnostics

K061794

NOV 2 1 2006

Premarket Notification 510(k) Summary

Assigned 510(k) Number:

1. Submitted by :

Name:	Biomedical Diagnostics S.A (bmd)
Contact Person:	Christelle COURIVAUD Regulatory Affairs Manager
Address:	Actipole 25, 4-6 Bld de Beaubourg 77435 Marne-La-Vallée Cedex 2 FRANCE
Telephone:	33 (0)1 64 62 10 12
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Establishment Registration Number:	3003935253

US Agent correspondent:

Hoppe Regulatory Consultants
Ms P. Ann HOPPE
2335 Massey Lane
Decatur GA 30033 USA
Phone: 404 248 0002
E-mail: Hoppe Regulatory@cs.com

2. Device Name

Trade/Proprietary Name :	**FIDIS™ THYRO**
Common/Usual Name :	**MX002 - FIDIS™ THYRO**: Detection test of autoantibodies directed against thyroperoxydase (TPO) and thyroglobuline (TG).
Classification Name:	Immunology and Microbiology Devices

3. Predicate Devices

510K Number	Device Classification Name	Manufacturer Name
K905485	IMMUNOWELL THYROGLOBULIN TEST	General Biometrics, INC
K905486	IMMUNOWELL TPO (MICROSOME) TEST	General Biometrics, INC

S.A au Capital de 2 755.46 Euros
RCS Meaux: B 339 685 612
Siret: 339 685 612 00048-APE: 514N
N° TVA Intracommunautaire: FR 68 339 685 612

Registered Office :
Actipole 25
4-6 bd de Beaubourg
77435 Marne La Vallée cedex 2

Tel: 33 (0)1 64 62 10 12
Fax : 33 (0)1 64 62 09 66
Email: bmd@bmd-net.com
Internet : www.bmd-net.com

4. Intended use of the device

The **FIDIS™ THYRO** kit is a semi-quantitative homogeneous fluorescent-based microparticles immunoassays using flow cytometry readings. It is designed for the detection of antibodies directed against thyroperoxydase (TPO) and thyroglobuline (TG).

The presence of these antibodies can be used to aid in the diagnosis of auto-immune thyroid pathologies (Grave's disease and Hashimoto's thyroiditis).

5. Description of the Device

The assay kits consist of:
- a vial of color-coded microspheres coupled with thyroperoxydase (TPO) or thyroglobulin (TG)
- a ready to use anti-human IgG coupled to phycoerythrin,
- a ready to use calibrator titered for the specificity,
- a positive control IgG to be diluted,
- a negative control to be diluted,
- a 10X concentrated PBS-Tween.

Rk: Calibrators, positive and negative controls are diluted human sera.

6. Summary of the technological characteristics of the device compared to the predicate device

The **FIDIS™ System** is a fully integrated and automated system for immunodiagnostic testing.
FIDIS™ System comprised of FIDIS flow cytometer, XYP platform for automatic sampling into the analyser, the analyzer itself, a SD pump, some FIDIS™ kits and a software **MLX-BOOSTER**.

The **FIDIS™ THYRO** kit resembles traditional EIA and allows the detection and identification of antibodies against thyroperoxydase (TPO) and thyroglobuline (TG).

1. Diluted patient sera and microsphere suspension are thoroughly mixed in the 96 well microtiter plate. TPO or TG specific antibodies in the patient sera, if present, bind to the immobilised antigen on the beads. Any unbound material is removed by performing a wash step.
2. Phycoerythrin-conjugated goat anti-human IgG is added to the plate and a further incubation performed. The conjugated anti-human IgG binds to the TPO or TG specific antibodies immobilised on the microsphere surface to form an antigen/antibody complex.

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3. The bead suspension is then analysed by the FIDIS™ Instrument and reactions are directly calculated in biological units using specific data software (**MLX-BOOSTER**).

The **FIDIS™ Instrument** is able to distinguish the specific color-coded of the microsphere and it could associated the microsphere type with the individual tested antigen.
The **FIDIS™ Instrument** could quantify the fluorescence of the antibody captured by each microsphere. Measurement of the fluorescent signal from the final reaction complex allows the quantification of the presence or absence of autoantibodies.

7. Testing

The comparability of predicate devices and new devices is supported by a data set including:

- results obtained within a comparison study analysing positive, equivocal and negative sera
- results obtained for samples from apparently healthy subject (normal population)
- results obtained for samples from samples with potential biological cross reactivity

8. Conclusions

In conclusion, all available data support that the new devices, **FIDIS™ THYRO** kit is substantially equivalent to the predicate devices.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Biomedical Diagnostics (BMD) SA
c/o Ms. Christelle Courivaud
Regulatory Affairs Manager
Actipole 25, 4-6 Bld de Beaubourg
77435 Marne-La-Vallée Cedex 2
France

NOV 2 1 2006

Re: k061794
Trade/Device Name: FIDIS™ THYRO
Regulation Number: 21 CFR 866.5870
Regulation Name: Thyroid Autoantibody Immunological Test System
Regulatory Class: Class II
Product Code: JZO, JNL
Dated: June 16, 2006
Received: June 26, 2006

Dear Ms. Courivaud:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Robert L. Becker, Jr., M.D., Ph.D.
Director
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

510(k) Number (if Known): k061794

Device Name: **FIDIS™ THYRO**

Indications For Use:

The **FIDIS™ THYRO** kit is a semi-quantitative homogeneous fluorescent-based microparticles immunoassay using flow cytometry readings. It is designed for the detection of antibodies directed against thyroperoxydase (TPO) and thyroglobuline (TG).

Clinical utility:

The test system is used on serum samples as an aid in the diagnostic of auto-immune thyroid pathologies (Graves' disease and Hashimoto thryroiditis), in conjunction with clinical findings and other laboratory tests.

The **FIDIS™ THYRO** kit is to be used on FIDIS™ Analyser, software and washer.

Prescription Use ____X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K061794